07/28/04

1645
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Docket No: AM100221
Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of:	**CHU et al.**		
Application No.:	**09/887,296**	Group No.:	**1645**
Filed:	**June 21, 2001**	Examiner:	**Sarvamangala J N Devi**
For:	**METHODS AND COMPOSITION FOR ORAL VACCINATION**		
Confirmation No.:	**6853**		
Customer Number:	**25291**		

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

July 27, 2004

AMENDMENT ACCOMPANYING RCE

Sir:

This replies to the Office action mailed June 25, 2003, and the response includes a petition for a 3 month extension of time on a Notice of Appeal submitted herewith.. Reconsideration of this application, and claims 1-10 and 27-30, is respectfully requested in view of the hereinbelow remarks and amendments. The Notice of Appeal is submitted in the event this reply is not deemed to place the application in condition for allowance.

AMENDMENT TO THE CLAIMS

Please amend claims 1:
Claims 1 (currently amended),
Claims 2-3, 5-6, 8-10 (previously amended)
Claims 4, 7 (original)
Claims 27-30 (previously presented)
Claims 11-26 (withdrawn)

1. (Currently amended). A method of providing protection against a disease in a nonhuman animal comprising:
   (a) admixing a water soluble palatable flavorant selected from the group consisting of fruit, fish and meat flavorants with a water soluble vehicle suitable for an orally administered vaccine to create a mixture;
   (b) further admixing with the mixture of step (a), an antigen which is an active component selected from the group consisting of a bacterium and a virus to thereby produce an oral vaccine; and
   (c) administering the vaccine of step (b) to ~~an~~ said nonhuman animal to provide protection against a disease.

CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EV100495247 US** addressed to the Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

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Date

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2. (Previously amended). The method of claim 1, wherein the antigen is capable of causing a disease in a nonhuman animal selected from the group consisting of swine, poultry, cattle, sheep goats, horse, cat and dog.

3. (Previously amended). The method of claim 2, wherein the antigen is selected from the group consisting of *Erysipelothrix rhusiopathiae*, *Actinobacillus pleuropneumoniae*, *Mycoplasma hyopneumonia*, *E. coli K88*, *K99*, *F41* and *987P*, *Clostridium perfringens type c*, *Salmonellacholeraesuis*, *Bordetella bronchiseptica*, *Leptospira bratislava*, *Leptospira canicola*, *Leptospira grippotyphosa*, *Leptospira hardjo*, *Leptspira Pomona*, *Leptospira canicola*, Porcine Influenza virus, Circovirus, Porcine Reproductive and Respiratory Syndrome (PRRS) virus, Swine pox, Rotavirus, Porcine Respiratory Coronavirus, Parvo virus, Pseudorabies, transmissible gastroenteritis agent, *Streptococcus equi*, *Clostridium tetanus*, Equine Influenza Virus A1 and A2 strains, Equine Rhinopneumonids type 1, 1b and 4, Eastern Equine Encephalomyelitis, Western Equine Encephalomyelitis, Venezuelan Equine Encephalomyelitis, Equine Rotavirus, *E. coli O157:H7*, *Pasteurella multocida*, *Pasteurella haemolytica*, *Clostridium perfringens type D*, *Clostridium chauvoel*, *Clostridium novyl*, *Clostridium septicum*, *Clostridium haemolyticum*, *Clostridium sodellii*, *Salmonella dublin*, *Salmonella typhimurium*, Bovine Rotavirus, Bovine coronavirus, Bovine rhinotracheitis, Bovine diarrhea virus, Parainfluenza-3, Respiratory syncytial virus, *Sepullina pilosicoli*, Marek's disease virus, Infectious bursal disease, Infectious bronchitis, Newcastle disease virus, Reo virus, Turkey rhinotracheltis, Couidiosis, Canine *Borrelia burgdorferi*, Canine *Ehrlichia canis*, Canine *Bordetella bronchiseptica*, Canine *Giardia lamblia*, Canine distemper, Canine Adenovirus, Canine Coronavirus, Canine Parainfluenza, Canine Parvovirus, Canine Rabies, Feline *Chlamydia psittaci*, Feline immunodeficiency virus, Feline infectious peritonitis virus, Feline leukemia virus, Feline rhinotrachelitis, Feline Panleukopenia, and Feline rabies.

4. (Original). The method of claim 1, wherein the vaccine is administered through drinking water.

5. (Previously amended). The method of claim 1, wherein the nonhuman animal is selected from the group consisting of swine, poultry, cattle, sheep, goats, horse, cat and dog.

6. (Previously amended). The method of claim 1, wherein the nonhuman animal is selected from the group consisting of swine and poultry.

7. (Original). The method of claim 6, wherein the administration of the orally administered vaccine is a mass administration through drinking water.

8. (Previously amended). The method of claim 7, wherein the nonhuman animal is a pig and the antigen is *Erysipelothrix rhusiopathiae*.

9. (Previously amended). The method of claim 1, wherein the nonhuman animal is selected from the group consisting of dog and cat.

10. (Previously amended). The method of claim 7, wherein the administration of the orally administered vaccine is into the mouth through a syringe.

11. (Withdrawn). A method of inducing increased intake of an orally administered vaccine by an animal comprising:
(a) admixing a water soluble palatable flavorant with a water soluble vehicle for administration of an orally administered vaccine;

(b) further admixing with the mixture of step (a), an antigen selected from the group consisting of a bacterium and a virus as an active component of the orally administered vaccine; and
(c) administering the vaccine admixture of step (b) orally to the animal;
(d) inducing the increased intake of the orally administered vaccine with the flavorant.

12. (Withdrawn). The method of claim 11, wherein the antigen is capable of causing disease in an animal selected from the group consisting of swine, poultry, cattle, sheep, goats, horse, cat and dog.

13. (Withdrawn). The method of claim 12, wherein the antigen is selected from the group consisting of *Erysipelothrix rhusiopathiae, Actinobacillus pleuroneumonla, Mycoplasma hyopneumonlae, E. coli K88, K99, F41 and 987P, Clostridium perferingens type c, Salmonella choleraesuls, Pasterurella muitocida, Bordetella bronchiseptica, Leptospira bratislava, Leptospira canicola, Leptospira grippotyphosa, Leptospira hardjo, Leptospira promona, Leptospira ictero,* Porcine Influenza virus, Circovirus, PRRS virus, Swine pox, Rotavirus, Porcine Respiratory Coronavirus, Parvo virus, Pseudorabies, transmissible gastroenteritis agent, *Streptococcus equi, Clostridium tetanus,* Equine Influenza Virus A1 and A2 strains, Equine Rhinopneumonids type 1, 1b and 4, Eastern Equine Encephalomyelitis, Western Equine Encephalomyelitis, Venezuelan Equine Encephalomyelitis, Equine Rotavirus, *E. coli O157:H7, Pasterurella multocida, Pasterurella haemolytica, Clostridium perferingens type D, Clostridium chauvoel, Clostridium novyl, Clostridium septicum, Clostridium haemolyticum, Clostridium sodellii, Salmonella dublin, Salmonella typhimurium*, Bovine Rotavirus, Bovine coronavirus, Bovine rhinotracheitis, Bovine diarrhea virus, Parainfluenza-3, Respiratory syncytial virus, *Sepullina pilosicoli,* Marek's disease virus, Infectious bursal disease, Infectious bronchitis, Newcastle disease virus, Reo virus, Turkey rhinotracheltis; Couidiosis, Canine *Borrella burgdorferi,* Canine *Ehrlichia canis,* Canine *Bordetella bronchiseptica,* Canine *Giardia lamblia,* Canine distemper, Canine Adenovirus, Canine Coronavirus, Canine Parainfluenza, Canine Parvovirus, Canine Rabies, Feline *Chlamydia psittaci*, Feline immunodeficiency virus, Feline infectious peritonitis virus, Feline leukemia virus, Feline rhinotrachelitis, Feline Panleukopenia, Feline rabies.

14. (Withdrawn). The method of claim 11, wherein the vaccine is administered through drinking water.

15. (Withdrawn). The method of claim 11, wherein the animal is selected from the group consisting of swine, poultry, cattle, sheep, goats, horse, cat and dog.

16. (Withdrawn). The method of claim 15, wherein the animal is selected from the group consisting of swine and poultry.

17. (Withdrawn.) The method of claim 16, wherein the administration of the orally administered vaccine is a mass administration through drinking water.

18. (Withdrawn). The method of claim 17, wherein the animal is swine and the antigen is *Erysipelothrix rhusiopathiae.*

19. (Withdrawn). The method of claim 11, wherein the animal is selected from the group consisting of dog and cat.

20. (Withdrawn). The method of claim 19, wherein the administration of the orally administered vaccine is at the back into the mouth through a syringe.

21. (Withdrawn). An orally administered animal vaccine formulation comprising as an active component an antigen selected from the group consisting of a bacterium and a virus, a water soluble palatable flavorant and a water soluble vehicle for administration of the orally administered animal vaccine.

22. (Withdrawn). The vaccine formulation of claim 21, wherein the antigen is capable of causing disease in an animal selected from the group consisting of swine, poultry, cattle, sheep, goats, horse, cat and dog.

23. (Withdrawn). The vaccine formulation of claim 22, wherein the antigen is selected from the group consisting of *Erysipelothrix rhusiopathiae, Actinobacillus pleuroneumonla, Mycoplasma hyopneumonlae, E. coli K88, K99, F41 and 987P, Clostridium perferingens type c, Salmonella choleraesuls, Pasterurella muitocida, Bordetella bronchiseptica, Leptospira bratislava, Leptospira canicola, Leptospira grippotyphosa, Leptospira hardjo, Leptospira promona, Leptospira ictero,* Porcine Influenza virus, Circovirus, PRRS virus, Swine pox, Rotavirus, Porcine Respiratory Coronavirus, Parvo virus, Pseudorabies, transmissible gastroenteritis agent, *Streptococcus equi, Clostridium tetanus,* Equine Influenza Virus A1 and A2 strains, Equine Rhinopneumonids type 1, 1b and 4, Eastern Equine Encephalomyelitis, Western Equine Encephalomyelitis, Venezuelan Equine Encephalomyelitis, Equine Rotavirus, *E. coli O157:H7, Pasterurella multocida, Pasterurella haemolytica, Clostridium perferingens type D, Clostridium chauvoel, Clostridium novyl, Clostridium septicum, Clostridium haemolyticum, Clostridium sodellii, Salmonella dublin, Salmonella typhimurium*, Bovine Rotavirus, Bovine coronavirus, Bovine rhinotracheitis, Bovine diarrhea virus, Parainfluenza-3, Respiratory syncytial virus, *Sepullina pilosicoli,* Marek's disease virus, Infectious bursal disease, Infectious bronchitis, Newcastle disease virus, Reo virus, Turkey rhinotracheltis, Couidiosis, Canine *Borrella burgdorferi,* Canine *Ehrlichia canis,* Canine *Bordetella bronchiseptica,* Canine *Giardia lamblia,* Canine distemper, Canine Adenovirus, Canine Coronavirus, Canine Parainfluenza, Canine Parvovirus, Canine Rabies, Feline *Chlamydia psittaci*, Feline immunodeficiency virus, Feline infectious peritonitis virus, Feline leukemia virus, Feline rhinotrachelitis, Feline Panleukopenia, Feline rabies.

24. (Withdrawn). The vaccine formulation of claim 21, wherein the vehicle for administration is drinking water.

25. (Withdrawn). The vaccine formulation of claim 21, wherein the animal is a swine and the antigen is *Erysipelothrix rhusiopathiae.*

26. (Withdrawn). The vaccine formulation of claim 21, wherein the animal is selected from the group consisting of a dog and a cat and the vehicle for administration is a syrup.

27. (Previously presented). The method of claim 7 wherein the water soluble palatable fruit flavorant is selected from the group consisting of cherry, grape, watermelon, and apple.

28. (Previously presented). The method of claim 7 wherein the water soluble palatable fruit flavorant is strawberry.

29. (Previously presented). The method of claim 1 wherein the water soluble palatable flavorant is a fruit flavorant.

30. (Previously presented). The method of claim 29 wherein the fruit flavorant is strawberry.

REMARKS

The present invention is directed to compositions and methods for the oral vaccination of healthy animals through drinking water or syrups as an aid in the prevention of disease, and is particularly applicable compositions and methods for mass vaccination.

35 U.S.C. § 112, 1st & 2nd paragraph Consideration/Rejection

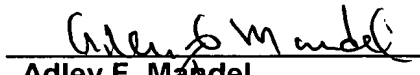
The Examiner in the Advisory Action did not enter the amendments made in applicants' reply dated December 24, 2003, stating that the limitation "nonhuman" added to the claims was newly presented, and raised new issues requiring consideration and/or searches under 35 USC 112, first paragraph.

The Examiner also stated that the failure in the December 24, 2003, reply of applicant to amend the phrase "an animal" in part (c) of claim 1, after amending claim 1 to read on a "nonhuman" animal, required a new rejection under 35 USC 112, second paragraph, as claim would otherwise be indefinite and confusing. This prospective rejection is now traversed with the amendment to claim 1.

Reconsideration of this application and the rejection of all pending claims is respectfully requested in view of the hereinabove amendment and remarks, the amendment and remarks made in applicants' "Amendment and Reply After Final Rejection", submitted December 24, 2003, (and enclosed for convenience with the RCE transmittal) and the issuance of a Notice of Allowance is earnestly solicited.

Because the number of claims has not been changed by this amendment, it is not accompanied by a transmittal letter. If any additional fees are required by this paper or the accompanying papers, the Patent Office is authorized to charge such fees to Deposit Account No. 01-1425.

Respectfully submitted,



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Application No.:	**09/887,296**	Group Art No.:	**1645**
Filed:	**June 21, 2001**	Examiner:	**Sarvamangala J N Devi**
For:	**METHODS AND COMPOSITION FOR ORAL VACCINATION**		
Confirmation No.:	**6853**		
Customer Number:	**25291**		

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RESPONSE

Sir:

This responds to the Office action mailed July 7, 2004, in which applicants were advised that the amended document (i.e., "Amendment Accompanying RCE") filed and dated on 6-24-04 was considered non-compliant under 35 CFR 1.121, in that a complete listing of all the claims was not present.

After review, it appears the non-compliance related to the fact that the offending amendment did not, on page 1 therein, refer to withdrawn claims 11-26, nor did the body of the amendment reproduce the text of those withdrawn claims.

Accordingly, and in complete response to the Notice of Non-Compliant Amendment, applicants resubmit the now compliant Amendment Accompanying RCE, as attached. The changes in the amendment are the listing and reference to withdrawn claims 11-26 on page 1 of the amendment, and the reproduction of the text of claims 11-26 with prefix phrase, "(Withdrawn)."

Additionally, applicants corrected reference to claims 27-30 to note that they are "previously presented" claims – i.e., they were presented in an amendment filed April 11, 2003.

In view of the foregoing, reconsideration of this application and the rejection of all pending claims is again respectfully requested in view of the amendment and remarks made in applicants' previous "Amendment and Reply After Final Rejection", submitted December 24, 2003, the attached resubmitted, now compliant Amendment Accompanying RCE. Issuance of a Notice of Allowance is earnestly solicited.

CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EV100495247 US** addressed to the Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

July 27, 2004
Date

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Because the number of claims has not been changed by this Response, it is not accompanied by a transmittal letter. If any additional fees are required by this paper or the accompanying papers, the Patent Office is authorized to charge such fees to Deposit Account No. 01-1425.

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